

HMA WGEO – Rapid Alert Form

Counterfeit or illegal product found in the illegal supply chain

Shaded area to be completed by the secretariat

Reference: No: 22DIS022	
Date: 06.04.2022	Time: 12:30 Initials: KDK
Please complete sections 1 to 5 providing as much information as possible.	
1. REPORTING PERSON	
Name:	Position:
Organisation:	
Address:	
Telephone	
e-mail address:	
2. PRODUCT DETAILS	
Reference samples with human thrombin (component of the medical device Surgiflo Haemostatic Matrix kit – Ferrosan)	
Manufacturer: Patheon (Ferentina – Italy)	
Supplier: Omrix EU	
Legal status: Banned <input type="checkbox"/> Counterfeit <input type="checkbox"/> Unlicensed <input type="checkbox"/> Stolen <input checked="" type="checkbox"/>	
Dosage form: Vials for reconstitution	
Strength: N/A	
Batch / lot no: 21LTF41A	
Is batch number genuine: Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
If yes to the above, advise batch destination country: N/A Samples	
Expiry date: 09/2023	
Language of packaging: English	
Date of discovery: 23.11.2021	
52 vials of reference samples with human thrombin were reported lost during transportation. The shipment was send by air from the production site in Ferentina, Italy to the distribution warehouse Omrix EU in Strasbourg, France. The transporter was DHL. After unloading the plane, the container with this shipment appeared lost and was not recovered so far. A second container that was in the shipment arrived in good order at destination.	

Analysed: YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>
If yes, result of analysis: -

3. DISTRUBUTION METHOD

Internet: YES <input type="checkbox"/> / NO <input checked="" type="checkbox"/>	
Internet: -	So far, we have no indications that the products have been introduced in the legal distribution chain.
URL: -	
Website address: -	
Other details: -	
Currency of payment: -	
Has product reached patients/consumers? Unknown	

4. RISK TO PUBLIC HEALTH

Adverse reactions: YES <input type="checkbox"/> / NO <input checked="" type="checkbox"/>
Medical assessment details: N/A

5. NEED FOR PUBLICITY

Are you making a public statement? YES <input type="checkbox"/> / NO <input checked="" type="checkbox"/>
Are you issuing a press release? YES <input type="checkbox"/> / NO <input checked="" type="checkbox"/>
Are you recalling product? YES <input type="checkbox"/> / NO <input checked="" type="checkbox"/>

6. DISSEMINATION

Are you content for this Rapid Alert to be shared outside WGEO membership? YES <input type="checkbox"/> / NO <input checked="" type="checkbox"/> (please see below)
If yes, please specify which of the below you are content for this to be shared with (you may tick more than 1 box) Law Enforcement <input type="checkbox"/> Industry Security <input type="checkbox"/> Trade Associations <input type="checkbox"/> Traders <input type="checkbox"/> Other <input type="checkbox"/> Please specify _____

7. PHOTOGRAPH

If possible, please attach a photograph of the product.

